

Herceptin®
Trastuzumab

Targeted on HER2. Focused on living.

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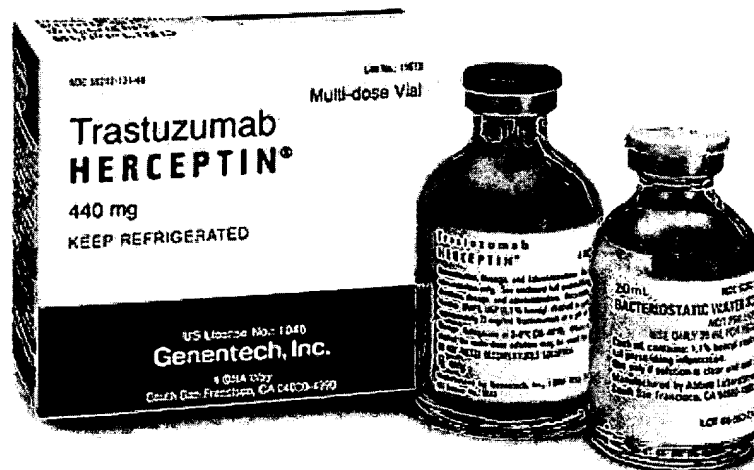
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Prescribing Information
& Boxed WARNING**Dosage and Administration****Reconstitution and preparation**

Herceptin® (Trastuzumab) is packaged as one preservative-free 440-mg vial of Herceptin (lyophilized) and one 20-mL vial of bacteriostatic water for injection (BWFI), USP, containing 1.1% benzyl alcohol as a preservative. Using aseptic technique, reconstitute Herceptin with **ONLY 20 mL** of the supplied BWFI; this yields a multidose solution containing 21 mg/mL Herceptin at a pH of approximately 6.[1]

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For patients with a known hypersensitivity to benzyl alcohol (the preservative in bacteriostatic water for injection), Herceptin must be reconstituted with sterile water for injection (SWFI), USP (see Precautions in full Prescribing Information). HERCEPTIN WHICH HAS BEEN RECONSTITUTED WITH SWFI MUST BE USED IMMEDIATELY AND ANY UNUSED PORTION DISCARDED. USE OF OTHER RECONSTITUTION DILUENTS SHOULD BE AVOIDED.[1]

Dosage

Determine the number of mg of Herceptin needed based on a loading dose of 4 mg/kg body weight, or a maintenance dose of 2 mg/kg body weight. The weekly maintenance dose can be continued until disease progression.[1]

To calculate the dosage, convert the patient's weight into kilograms, then insert this number into the following equation, using either 4 mg (for a loading dose) or 2 mg (for a maintenance dose) as the multiplier:

Kilogram conversion:

$$\frac{\text{patient weight in pounds}}{2.2} = \text{patient weight in kilograms}$$

Dosage calculation:

$$\frac{\text{patient weight in kg x multiplier (2 or 4 mg/kg)}}{21 \text{ mg/mL}} = \text{mL reconstituted Herceptin solution}$$

Add the calculated amount of reconstituted Herceptin solution to 250 mL of 0.9% sodium chloride, USP. **DO NOT USE DEXTROSE 5% SOLUTION.**[1]

Outpatient administration

Administer a 4-mg/kg loading dose as an infusion over 90 minutes. A 2-mg/kg weekly maintenance dose can be administered as a 30-minute infusion if the prior dose was well tolerated. **DO NOT ADMINISTER AS AN IV PUSH OR BOLUS.** Herceptin should not be mixed or diluted with other drugs.[1]

Stability

Keep the multidose solution refrigerated at 2-8°C (36-46°F). When reconstituted with BWFI, USP (1.1% benzyl alcohol), the multi-dose Herceptin solution may be used for 28 days, when stored refrigerated at 2-8°C (36-46°F). **DO NOT FREEZE OR SHAKE RECONSTITUTED SOLUTION.**[1]

The solution of Herceptin diluted with 0.9% sodium chloride injection, USP, may be stored at 2-8°C (36-46°F) for up to 24 hours prior to use.[1]

Herceptin administration as conducted in clinical trials

Herceptin in Combination

Day 0: Herceptin Administration—

Herceptin loading dose: 4 mg/kg over 90 minutes. Observe for 60 minutes. Start 20 mg oral dexamethasone (or equivalent) at 12 hours and 6 hours prior to paclitaxel.[1,2]

Day 1: Chemotherapy Administration—

Standard premedication: Start 50 mg IV diphenhydramine (or equivalent) 30 minutes prior to paclitaxel and 300 mg IV cimetidine (or other H2 blocker) 30 minutes prior to paclitaxel. Anthracyclines and cyclophosphamide (AC) or paclitaxel standard dose. [1,2]

Day 7 and 14: Herceptin Weekly Administration—

Herceptin maintenance dose: 2 mg/kg over 30 minutes, if prior infusion was well tolerated. Observe for 30 minutes. [1,2]

Day 21 (Day 1 of next chemotherapy cycle): Herceptin Plus Chemotherapy Weekly Administration—

Herceptin maintenance dose: 2 mg/kg over 30 minutes. (Start 20 mg oral dexamethasone [or equivalent] on day 21 at 12 hours and 6 hours prior to paclitaxel). Observe for 30 minutes. Standard premedication: Start 50 mg IV diphenhydramine (or equivalent) 30 minutes prior to paclitaxel and 300 mg IV cimetidine (or other H2 blocker) 30 minutes prior to paclitaxel. AC or paclitaxel standard dose. Continue Herceptin until disease progression. [1,2]

Herceptin in Monotherapy**Day 0: Herceptin Administration—**

Herceptin loading dose: 4 mg/kg over 90 minutes. Observe for 60 minutes. [1,2]

Day 7, 14, 21, etc:

Herceptin maintenance dose: 2 mg/kg over 30 minutes, if first infusion was well tolerated. Observe for 30 minutes. Continue Herceptin until disease progression. [1,2]

See What's Next...

For complete information on Herceptin® efficacy, safety, mechanism of action, pharmacology, and dosage and administration, please click [Prescribing Information](#) & [Boxed WARNING](#).

Related Links

Clinical Efficacy
Safety

1. Herceptin® (Trastuzumab) full Prescribing Information; October 2003.
2. Genentech, Inc. Data on file.
3. Simon R, Nocito A, Hubscher T, et al. Patterns of HER-2/neu

amplification and overexpression in primary and metastatic breast cancer. *J Natl Cancer Inst.* 2001;93:1141-1146.

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